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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	9

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Applicants' election (paper No. 7, filed 10/27/00) is non-responsive to the restriction mailed 9/29/00.

Further discussion of this matter may be found on the attached sheets.

SUBSTITUTE PTOL-90

Applicants' election of Group I with traverse is acknowledged. However, applicants have mischaracterized the invention of Group I, and secondly, applicants have failed to elect a specie; **applicants election is non-responsive**. Group I is not in fact drawn to claims 1-6 and 8-10 in their entirety; instead, Group I includes claims 1-6 and 8-10 to the extent that they encompass G1 and exclude G2.

With respect to the restriction between Groups I and II, applicants have argued that restricting a claim into two parts is "of course [improper]". However, applicants are not correct. Consider the following hypothetical example:

> 1. A physical entity.
>
> 2. A physical entity according to claim 1 selected from the group consisting of an automobile transmission, an aircraft, and an oceanliner.
>
> 3. A physical entity according to claim 1 selected from the group consisting of a DRAM chip, a computer disk drive, and a printing device.
>
> 4. A physical entity according to claim 1 selected from the group consisting of a monoclonal antibody, a steroid, an beta-lactam, and a thrombin inhibitory peptide.

Clearly, one examiner could not examine all of these inventions. This is admittedly an extreme example, but the point is that a single claim can serve as a "shell" or "umbrella" for a vast array of patentably distinct inventions. Applicants have essentially taken the position that the issue of multiple inventions must be considered only from the perspective of the claims as originally filed, and that examiners should completely disregard the question

of how many distinct inventions may really be contained within the independent claim(s) as presented at the time of restriction. Another example of a claim is offered:

> *5. A method of improving the quality of life of a person comprising the step of administering a compound to that person.*

Certainly this claim would be quite vulnerable to §102 rejections, but that is not the point. This claim (hypothetical claim 5) could encompass millions of different inventions, including therapy of disease, and nutrition. Moving on to the specific claims at hand, there is nothing to prevent applicants (after the first Office action on the merits) from cancelling claim 1, and submitting the following three claims:

> *11. A method of increasing protein synthesis in the intestine, the duodenum, or the jejunum of a patient comprising the step of administering a protein hydrolyzate to said patient.*
>
> *12. A method of maintaining muscle protein synthesis in a patient comprising the step of administering a protein hydrolyzate to said patient.*
>
> *13. A method of treating muscular atrophy in a patient comprising the step of administering a protein hydrolyzate to said patient.*

Thus, it is maintained that claim 1 encompasses at least two patentably distinct inventions. On the other hand, if it is really true that claim 1 is novel without further limitation, then it is likely that the restriction would be withdrawn. In such a case, applicants' entire ground of traversal would be rendered moot. More likely however, some of the inventions encompassed by claim 1 will be novel, and some will not. Following the imposition of a §103 or a §102 rejection, and applicants acquiescence thereto, applicants will be put into

a position of having to admit that there is more than one invention, or alternatively to admit that, since there is only one invention, that one, single unified invention must be obvious over, or anticipated by, the prior art, and that the application is most appropriately abandoned. This latter possibility is the less likely of the two. Whatever the outcome, applicants argument with respect to double patenting will almost certainly be rendered moot. Most likely applicants will unveil multiple inventions (after the FAOM) and so a divisional application, if filed, would contain claims drawn to a distinct invention anyway. Notwithstanding the foregoing, the possibility of rejoining Groups I and II is not necessarily precluded. It is possible that applicants will introduce a limitation into the claims that make both Groups novel. In such a case, rejoining of the two groups might be considered.

Applicants have refused to elect a species. First, applicants have argued that the examiner's true agenda in requiring a species election is to compel applicants to introduce limitations into the claims. However, nothing could be further from the truth, and moreover, applicants reasoning in reaching this conclusion is not understood. In fact, there is not such requirement now, and moreover, there will be no requirement at any point in the future to impose limitations into the claims solely as a result of election of a specie. Of course, if there is a valid art rejection, a limitation may be required; in addition, the examiner may seek to compel applicants to supply limitations in order to achieve compliance with §112, first and second paragraphs. Notwithstanding the foregoing, in the event that applicants were to cancel claim 1, and replace it with 10 independent claims, each with

different limitations, those claims which did not encompass the elected specie would be subject to withdrawal from consideration. It is common practice, when claims are drawn to discreet compounds, to impose an "election of species" requirement. In such cases, it is more the rule than the exception that if all embodiments are novel, the applicants do not have to introduce limitations, other than what may be required for compliance with §112, first and second paragraphs. In the instant case, if the claims are novel as currently presented, no limitations will be required other than what may be required for compliance with §112, first and second paragraphs. And if some of the inventions encompassed by claim 1 are not novel (as asserted by the examiner), all of the claims that are present now, or in the future that (a) encompass the elected specie and (b) fall within the scope of Group I will be examined.

Applicants have requested that the examiner indicate which claim is generic. In response, at least claim 1 is generic. Applicants have also indicated that the examiner should list every possible specie. The examiner submits that this is not a requirement, or at least that if the examiner fails to list every possible specie, it is not the case that applicants are freed from the burden of electing a specie. It is not at all unusual for a given application to encompass 1,000,000,000,000,000,000,000,000,000,000 or more patentably distinct species. In such a case, a single examiner could not list all of them over the course of his or her lifetime. In the instant case, the species are not discreet compounds; they are mixtures (or more accurately a method of using them). It is not unusual for an applicant to claim a

compound or a mixture by defining it only partially. For example, a hypothetical applicant might be claiming a novel protein which he (or she) has not yet fully characterized. The applicant might then claim the protein as having the following properties:

(a) an N-terminal sequence Arg-Gly-Pro-Met-Ser;

(b) a molecular weight of 32 kD;

(c) is obtained from tissue culture "X".

The point is that there are many ways to define an invention; a specific structure is not necessarily required (in the chemical an biological arts). Given that a specific structure is not necessarily required in the claims, a specific structure for an elected specie should not be required either in such cases. In the instant case, applicants have themselves chosen to describe the various embodiments in ways that do not fully define the mixtures being used. There is nothing inherently "wrong" with that. But the fact that every single molecule in the mixture has not been accounted for does not mean that a species election cannot be required.

If applicants need further direction in electing the two required species, applicants should consider the following:

1) is the "dietary protein" in fact a protein, or is it hydrolyzed, or is it "free amino acids" as recited in claim 5...?

2) if the "dietary protein" is in fact a protein that is not hydrolyzed, what is the protein? [Applicants are not compelled, by virtue of the species election, to recite the name of the protein in the claims].

3) if the "dietary protein" is hydrolyzed, some information should be provided as to the degree of hydrolysis. For example, on page 9, line 19, it is stated that the degree of hydrolysis is 4.41%. On page 10, line 5, a degree of hydrolysis of 14% is disclosed. On page 12, line 3, a degree of hydrolysis of 17.3% is disclosed. Thus, applicants should have no trouble deciding on a degree of hydrolysis. In addition, since applicants have chosen to define their invention in terms of the weight % dipeptides and tripeptides (see claims 4 and 6), it is appropriate for the "specie" to be defined partly in terms of this parameter. Thus, applicants should supply a weight % dipeptides and tripeptides present in the mixture. [Applicants are not compelled, by virtue of the species election, to recite a degree of hydrolysis in any of the claims, nor are applicants compelled, by virtue of the species election, to recite a weight % dipeptides and tripeptides].

4) the presence or absence of a carbohydrate and fat in the formulation should also be specified.

The foregoing applies to one specie, i.e., that of the protein or mixture that is to be administered to the patient. A second species election (since applicants have elected Group I), is a specific "organ" or body part (e.g., intestine, duodenum, or jejunum).

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

As stated above, **applicants' election is non-responsive to the restriction.** The time period for response is reset pursuant to this Office action. Failure to elect species in

accordance to the foregoing will result in ABANDONMENT of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800